

RECENT REASSESSMENTS OF RADIATION RISK ESTIMATES: IMPLICATIONS FOR RADIATION PROTECTION

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Abstract—The publication of the 1988 report by the United Nations Scientific Committee on the Effects of Atomic Radiation represents a major step forward in the estimation of the levels of risk associated with exposure to ionizing radiation. Data are now available which quantify the effects of high doses received at high dose-rates in a number of organs and tissues as well as the whole body. The estimates of risk given by UNSCEAR for fatal cancers are up to four times higher than when the Committee last reported in 1977. The main reasons for this change are: firstly, the change in dosimetry of the Japanese survivors of the atomic bombing; and, secondly, the increased epidemiological follow up period, to 1985, which tends to confirm the relative risk model. Uncertainties exist, however, in the numbers of cancers which will arise in irradiated populations that are still alive, and in the extrapolation to low dose, low dose-rate risk factors.

Since, in radiological protection, the assumption is made of a linear relationship between dose and risk, it follows that in setting dose limits it is necessary to consider not only the risk per unit dose, but also the limit of tolerable or acceptable risk. In this paper, the question of the limitation of risk is addressed for both members of the public and those occupationally exposed. The same question is being addressed by the International Commission on Radiological Protection in the formulation of their new recommendations. The relationships between dose and risk can be used to speculate on the range of dose levels within which ICRP may set limits. Finally, it is emphasized that, because all exposures will be as low as reasonably achievable, actual doses received would be expected to be below the limits derived in the paper.

1. GENERAL

During the last 12 months it can hardly have escaped the notice of any person in the nuclear business—medicine or power—that our estimates of the risks from exposure to ionizing radiation have increased. The main reason is the new information from the survivors of the atomic bombs at Hiroshima and Nagasaki. The International Commission on Radiological Protection (ICRP) felt it necessary to make a statement following its meeting in Como in September 1987 (ICRP, 1987), and my own organization—NRPB—gave advice to our Government departments and agencies with regulatory responsibilities to consider the implications of the change in risk estimates for dose limits (NRPB, 1987).

The major addition to our information since last year has been the report of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) on human radiation carcinogenesis (UNSCEAR, 1988). This Committee has reviewed all the human epidemiological data to assess the risks associated with exposure to ionizing radiation and the full report should be published at about the end of 1988. The publication of this report signals an international consensus on the effects of human radiation exposure, albeit at high doses and high dose-rates. The problem

that remains is to interpret what this means at the low doses and low dose-rates to which workers and members of the public are exposed.

The setting of dose limits in radiation protection necessarily requires judgements to be made on the acceptability of additional risks which may be sustained by a workforce or imposed on the public. In this respect, the publication by the Health and Safety Executive of their views on the tolerability of risk (HSE, 1988) represents an attempt to quantify what is acceptable or tolerable. In this paper, I will present the data on radiation risk and risk acceptance and discuss their use for setting dose limits.

2. ESTIMATES OF THE RISK OF RADIATION-INDUCED CANCER IN HUMAN POPULATIONS

The estimates of risk that NRPB has made are based on the 1988 UNSCEAR review of the experience obtained from human population groups exposed to high doses of radiation (UNSCEAR, 1988). Although there are several such groups, including patients treated for ankylosing spondylitis and workers exposed in the radium luminizing industry, the single most important

source of information is from the survivors of the Hiroshima and Nagasaki atomic bombs. This population of more than 90,000 people represents the largest group exposed to significant whole body irradiation. The new risk estimates are largely based on the latest data on the Japanese which take account of two main changes.

The first is a revision of the dosimetry known as DS86 to allow, amongst other factors, for the high humidity in the air over the cities which substantially reduced the neutron dose. The earlier 1965 (T65DR) estimates were based on measurements in the dry atmosphere of the Nevada Desert. Improved estimates have also been made of tissue and organ doses, allowing for the shielding provided by buildings. The second change is that the number of excess cancers in the population has increased since UNSCEAR last reported in 1977 (UNSCEAR, 1977) due to the longer time for epidemiological follow-up to 1985.

Lifetime cancer experience is not yet available for any of the large epidemiological studies. Therefore, to project the overall cancer risk for an exposed population, it is necessary to use mathematical models that extrapolate, over time, data based only a limited period of the lives of the individuals. The two projection models that have been used in the past are:

- (a) the additive model which postulates that the annual risk of cancer arises after a period of latency and then remains constant over time; and
- (b) the multiplicative model in which the time distribution of the excess risk follows the same pattern as the time distribution of natural cancers, i.e. the excess (after latency) is given by a constant multiplying factor applied to the age-dependent incidence of natural cancers in the population.

The data now available provide a deeper insight into the applicability of the two models and UNSCEAR states in its 1988 (UNSCEAR, 1988) report that recent findings in Japan suggest the multiplicative risk projection model is the more likely, at least for some of the most common cancer types. NRPB has adopted the multiplicative model for estimating lifetime risks of most solid cancers.

An implication of the use of the multiplicative risk model is that for the majority of solid cancers it results in an increasing risk with time after exposure, following the increase in natural incidence with age. There are indications, at least in some groups exposed to radiation, that the excess risk of cancer starts to decline many years after exposure. This has been well documented for leukaemia, but has also been observed at long times after exposure in the case of solid cancers for the spondylitics and possibly for some other

irradiated groups. These results suggest that in the Japanese survivors the excess risk may ultimately decrease with time and thus multiplicative projection models applied over the lifetime could result in an over-estimate of the cancer risks.

For a population of all ages, the 1988 UNSCEAR report derives a fatal cancer risk following whole body γ -exposure at high dose and high dose-rate estimated, using the multiplicative model, at between 7 and $11 \times 10^{-2} \text{ Gy}^{-1}$. For a working population aged 25–64 yr the multiplicative model gives a risk of $7\text{--}8 \times 10^{-2} \text{ Gy}^{-1}$. This compares with the Committee's 1977 assessment (UNSCEAR, 1977) of $2.5 \times 10^{-2} \text{ Gy}^{-1}$ using the additive model. The Committee in its 1988 report gives an indication of the effect of different risk models at high doses by applying the additive model which gives a fatal cancer rate of $4\text{--}6 \times 10^{-2} \text{ Gy}^{-1}$ for a population of working age (25–64 yr) compared with $4\text{--}5 \times 10^{-2} \text{ Gy}^{-1}$ for a population of all ages. The data are summarized in Table 1 for the two models and both populations. The differences between the two populations are less for the additive model because they are not based on the natural cancer incidence which increases with age.

Table 1. Projected lifetime risks of fatal cancer following whole body γ -exposure to high doses at high dose-rate (10^{-2} Gy^{-1})

	Projection model	
	Multiplicative	Additive
<u>UNSCEAR 1988</u>		
Population of all ages	7–11	4–5
Working population (25–64 yr)	7–8	4–6
<u>UNSCEAR 1977</u>		
Population of all ages		2.5

In 1977, the Committee pointed to uncertainties in two directions: the value derived from high doses was an underestimate because no projection had been made into the future, but it was also an overestimate in the sense that the risk per unit dose at low doses and low dose-rates was believed to be lower than the estimates at high doses and high dose-rates. Extrapolation into the future is still uncertain because about two-thirds of the Japanese survivors are still alive and the additional cancer risk has still to be expressed. The exception is the risk of leukaemia which appears more certain as nearly all the excess now seems to have occurred. The problem of low doses and low dose-rates remains.

3. CANCER RISK ESTIMATES FOR PROTECTION PURPOSES

The assumption normally made for radiation protection purposes is that the risk of radiation-induced cancer is proportional to the dose, without threshold. For some human cancers, the dose-response data do suggest that the incidence of cancer is a linear function of the dose, at least for the dose range over which information is available. This applies to thyroid cancer, breast cancer and possibly to leukaemia following exposure to X- or γ -radiation at high dose-rates (UNSCEAR, 1986).

There is, however, information from animal studies which indicates that the induction of radiogenic cancer by X- or γ -radiation depends on the dose-rate and a dose-rate effectiveness factor (DREF) has been used by both UNSCEAR and ICRP to estimate the risk at low doses and dose-rates. At low dose-rates the numbers of cancers induced are lower by a factor of between two and ten than they are at high dose-rates (UNSCEAR, 1988; NCRP, 1980). Dose-response data for cancer induction have most recently been reviewed in detail by UNSCEAR (1986). It was concluded that for many cancers the assumption of a linear response when extrapolating from information at high doses and dose-rates could over-estimate risks at low doses and low dose-rates by a factor up to five. In the 1988 UNSCEAR report a DREF of between two and ten is quoted. Table 2 summarizes the results of reviews of dose-rate effectiveness factors.

Table 2. Summary of dose-rate effectiveness factors (DREF)

DREF		
UNSCEAR	1988	2-10
UNSCEAR	1986	up to 5
UNSCEAR	1977	2
NCRP	1980	2-10 (animal studies)
		3-4 (human leukaemia data)

The majority of the available animal data indicate a DREF of between two and four for the induction of cancer at low dose-rates compared with that calculated at high dose-rates. The figure that has been adopted by NRPB is three for all cancers except breast cancer for which a DREF of two is judged to be more appropriate.

4. RISK COEFFICIENTS FOR RADIATION-INDUCED FATAL CANCER IN THE U.K. POPULATION

The risks of radiation-induced cancer have been estimated by NRPB in a U.K. population of all ages

and both sexes. The full description of the derivation of the risks is given by Stather *et al.* (1988). The total lifetime fatal cancer risk in the U.K. population following whole body irradiation at low dose-rates is $4.5 \times 10^{-2} \text{ Gy}^{-1}$, over three times the ICRP figure from 1977 (ICRP, 1977). If the calculation is repeated using the cancer deaths that have actually occurred in the Japanese population in the 40 yr follow-up to 1985, and again transposing to the U.K. population, a whole body risk of $1.4 \times 10^{-2} \text{ Gy}^{-1}$ is obtained. This figure can be taken as the minimum value of risk so that the actual risk is from at least $1.4\text{--}4.5 \times 10^{-2} \text{ Gy}^{-1}$.

The fatal cancer risk estimated for a U.K. working population (ages 20-64 yr, both sexes) exposed to whole body radiation at low dose-rates is from at least $1.8\text{--}3.4 \times 10^{-2} \text{ Gy}^{-1}$, up to nearly three times the 1977 ICRP figure. The fatal cancer risks for protection purposes derived by NRPB are summarized in Table 3.

Table 3. Fatal cancer risk factors for radiation protection purposes in a U.K. population (10^{-12} Gy^{-1})

	Lifetime projection	Risk to date
Total population	4.5	1.4
Working population (20-64 yr)	3.4	1.8

For an overall assessment of the risk of cancer in a population information is required on incidence as well as fatalities. The fatality rate for all cancers is about two-thirds of incidence in the U.K. population and the breakdown for different organs is given by Stather *et al.* (1988).

5. NRPB INTERIM ADVICE ON STANDARDS FOR NORMAL OPERATION

The system of dose limitation recommended by the International Commission on Radiological Protection (ICRP, 1977) applies to the control of radiation exposure from normal operations including the exposures of radiation workers and the exposures of the public from routine discharges of gaseous and liquid radioactive effluents. The two requirements of the system which have most practical influence are that doses to individuals should not exceed the limits recommended by ICRP, and that all doses should be As Low As Reasonably Achievable (ALARA), economic and social factors being taken into account. The dose limits define the lower boundary of a region in

which exposures are unacceptable while the ALARA requirement gives a mechanism for decisions on how far below those limits it should be reasonable to strive to reduce doses. This means that it is not adequate just to demonstrate compliance with dose limits.

ICRP is currently reviewing its basic standards of protection and revised recommendations are expected to be completed by 1990. Given the evidence that was emerging regarding changes in the estimates of the risks of fatal cancer, NRPB in 1987 produced interim guidance (NRPB, 1987) for those with regulatory responsibility for setting dose limits for workers and the public, and for those involved in the management of those exposures. The guidance was based on an anticipated increase in the risk for fatal cancers by a factor of two or three.

This has been borne out by the UNSCEAR reports where, as described earlier, the risk factor for fatal cancer is taken to be about three times the previous value. We recommended that as long as the dose limit remained at 50 mSv per year the average dose to the most exposed workers should be so controlled as not to exceed an effective dose equivalent of 15 mSv per year. For the public, we recommended that, as the principal dose limit was already at 1 mSv per year, the doses to the most exposed groups from effluent discharges from nuclear installations should be so controlled as not to exceed an effective dose equivalent of 0.5 mSv per year for a single site.

6. TOLERABLE RISK

It has been the practice, in radiation protection, to assume linearity between dose and risk without threshold. Therefore any exposure to radiation—however small—is assumed to carry a proportionate amount of risk. There is no reason to change this assumption—there is no convincing evidence of a response greater or less than linear. It follows that the discussion on the limitation of risk to individuals must include not only the risk per unit dose but also what risks are acceptable.

For both workers and the public, a wide range of individual risk is accepted under different circumstances. Industrial fatal risks vary worldwide, but in the U.K. the range is from a few per million per year in shops and offices to over 100 per million per year in coal mining. The figures conceal higher risk subgroups—quarrying gives 1 in 2500 per year and fishermen on U.K. registered deep sea vessels have a 1 in 1100 per year fatal accident rate. There is no single, simple dividing line to distinguish those risks that are clearly unacceptable. Rather, there is a broad range of

risk within which dose limits are set for workers and the public.

To assess what might be acceptable risks, in GS9 we relied on the judgement of a Study Group of the Royal Society (1983), which we thought had probably reflected the current popular U.K. view on risk tolerability. This report was not specifically concerned with nuclear matters but *all* hazardous risks.

The Study Group decided that for someone of normal life expectancy, a continuing risk of 1 in 100 per year was unacceptable—you would almost certainly die from that cause. At 1 in 1000 per year, they thought the risk may not be totally unacceptable, if the individual knows of the situation, enjoys some commensurate benefit, and everything reasonable has been done to reduce the risk. This gives us an upper limit to occupational risk of about 10^{-3} per year.

For members of the public, the Royal Society's judgement was that there was a widely held view that few people would commit their own resources to reduce an annual risk of death which was already as low as 1 in 100,000. If, however, there are grounds for suspecting a real risk, at an annual level of 1 in 10,000, the imposition of that risk is likely to be challenged. It seems therefore that a reflection of society's present view is that an unacceptable *imposed* risk will be one at a level between 1 in 10,000 and 1 in 100,000 per year.

The Health and Safety Executive (HSE) has since published its views on the philosophy of risk control in a document entitled "The tolerability of risk from nuclear power stations" (HSE, 1988). It is appropriate to evaluate the levels of risk corresponding to NRPB's interim guidance on restricting radiation exposure (NRPB, 1987) and to compare those levels with HSE's proposals. The tolerability of risk document proposes an upper level of occupationally fatal risk of 10^{-3} per year. For a U.K. workforce the fatal cancer risk is taken to be $3.4 \times 10^{-2} \text{ Sv}^{-1}$ to which we now believe should be added $0.8 \times 10^{-1} \text{ Sv}^{-1}$ for serious hereditary defects in all future generations, rather than just the defects in the first two generations included by ICRP. I believe that some allowance in the estimate of total risk should be made for non-fatal cancers. Total cancers arise at a rate of about 1.5 times the fatality rates, but non-fatal cancers might be weighted by 0.1 or 0.2 to give them only a fraction of the importance of a fatality. Summing these health effects gives an equivalent occupational risk rate of about $4.5 \times 10^{-2} \text{ Sv}^{-1}$ which, if NRPB's interim advice (NRPB, 1987) is followed and doses for the most exposed individuals average 15 mSv per year, gives an annual risk of 7×10^{-4} . This is below the HSE tolerable limit of 10^{-3} per year.

For members of the public a similar calculation.

based on the risk factors in Section 4, would give an equivalent risk of about $6 \times 10^{-2} \text{ Sv}^{-1}$, which, taking the principal dose limit of 1 mSv per year, corresponds to an annual risk of 6×10^{-5} , below HSE's suggested tolerable limit of 10^{-4} per year and at the upper end of the range suggested by the Royal Society's group. Table 4 summarizes the risks corresponding to present dose limits and NRPB's interim advisory doses in comparison with HSE's limits of tolerable risk.

Table 4. Annual risk levels corresponding to continuous exposure at certain levels of dose

Annual dose	Annual risk
Occupational	
50 mSv—ICRP and U.K. limit	2×10^{-3}
15 mSv—NRPB interim guidance	7×10^{-4}
HSE limit of tolerable risk	10^{-3}
Public	
1 mSv—ICRP principal limit	6×10^{-5}
0.5 mSv—NRPB interim guidance	3×10^{-5}
HSE limit of tolerable risk	10^{-4}

7. CONCLUSION

What I have been talking about is *upper* limits to risk. The problem for ICRP, and then national authorities, is to decide on tolerable risk levels, the risk per unit dose figure to adopt and then to set the dose limits for workers and the public. But we are talking about *limits*; beneath this there is the whole structure

of ensuring doses are as low as reasonably achievable (ALARA). This should result in most doses being well below any limits set in the near future.

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